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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,177	02/26/2002	Christopher R. Tudan	SMAR-012CIP	1250

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,177	TUDAN ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is noted to Applicant that claims 9 and 23 do not constitute proper Markush groups because there is no "alternative" language recited between parts (a)-(c) (see MPEP §2173.05(h)). Therefore, for restriction purposes, the Examiner has interpreted parts (a), (b), (c) of the claims to read on "and" terminology.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-15, drawn to a method of reducing the rate of hematopoietic cell multiplication comprising administering an effective amount of a peptide CXCR4 agonist to the hematopoietic cells, classified in class 435, subclass 4.

   II. Claims 1-16, drawn to a method of reducing the rate of hematopoietic cell multiplication comprising administering an effective amount of a nucleic acid encoding a CXCR4 agonist to the hematopoietic cells, classified in class 514, subclass 44.

   III. Claims 17-22, drawn to a method of reducing the susceptibility of hematopoietic cells to a cytotoxic agent comprising administering an effective amount of a CXCR4 agonist to the hematopoietic cells prior to or during exposure of the cells to the cytotoxic agent, classified in class 435, subclass 4.

   IV. Claims 23-26, drawn to a CXCR4 agonist peptide, classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

   a. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of reducing the rate of hematopoietic cell multiplication using a peptide CXCR4 agonist (Group I), the method of reducing the rate of hematopoietic cell multiplication using a nucleic acid encoding a CXCR4 agonist (Group II), and a method of reducing the susceptibility of

hematopoietic cells to a cytotoxic agent using a CXCR4 agonist (Group III) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for reducing the rate of hematopoietic cell multiplication differ significantly for each of the materials. For reducing the rate of hematopoietic cell multiplication using the peptide CXCR4 agonist, the CXCR4 agonist is administered to a subject using any mode of administration. For reducing the rate of hematopoietic cell multiplication using the nucleic acid encoding a CXCR4 agonist, the nucleic acid molecule is administered to a subject using any mode of administration. Finally, for reducing the susceptibility of hematopoietic cells to a cytotoxic agent using an effective amount of a CXCR4 agonist to the hematopoietic cells, the CXCR4 agonist is administered prior to or during exposure of the cells to the cytotoxic agent. Therefore, each method is divergent in materials and steps. For these reasons, Inventions I-III are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-III together.

b. Inventions IV and I/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the agonist peptide claimed can be used in materially different processes, such as diagnostic assays or immunoassays.

Searching the inventions of Groups IV and I/III together would impose serious search burden. The inventions of Groups IV and I/III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the CXCR4 agonist peptide and the methods of reducing the rate of hematopoietic cell multiplication and reducing the susceptibility of hematopoietic cells to a cytotoxic agent by using a CXCR4 agonist peptide are not coextensive. The search of Group IV would require a text search for the CXCR4 agonist peptide comprising an N-terminal sequence homologous to SDF-1, a C-terminal sequence homologous to SDF-1 or MIPα-1, and a peptide spacer. In contrast, the search for Groups I and III would require a text search for a method of reducing the rate of multiplication and a method of reducing the susceptibility of hematopoietic cells to a cytotoxic agent in addition to a search for a CXCR4 agonist peptide. Prior art which teaches a CXCR4 agonist peptide comprising an N-terminal sequence homologous to SDF-1, a C-terminal sequence homologous to SDF-1 or MIPα-1, and a peptide spacer would not necessarily be applicable to the method of using the CXCR agonist peptide. Moreover, even if the CXCR4 agonist peptide product was known, the method of reducing the rate of multiplication and reducing the susceptibility of hematopoietic cells to a cytotoxic agent which uses the product may be novel and unobvious in view of the preamble or active steps.

c. Inventions IV and II are unrelated because the product of group IV is not used or otherwise involved in the process of group II.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the**

patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Restriction to one of the following inventions is further required under 35 U.S.C. 121:

A. The inventions as they pertain to SEQ ID NO: 1, classification dependent upon the nature of the inventions.

B. The inventions as they pertain to SEQ ID NO: 2, classification dependent upon the nature of the inventions.

C. The inventions as they pertain to SEQ ID NO: 3, classification dependent upon the nature of the inventions.

D. The inventions as they pertain to SEQ ID NO: 4, classification dependent upon the nature of the inventions.

E. The inventions as they pertain to SEQ ID NO: 6, classification dependent upon the nature of the inventions.

F. The inventions as they pertain to SEQ ID NO: 8, classification dependent upon the nature of the inventions.

G. The inventions as they pertain to SEQ ID NO: 9, classification dependent upon the nature of the inventions.

H. The inventions as they pertain to SEQ ID NO: 10, classification dependent upon the nature of the inventions.

I. The inventions as they pertain to SEQ ID NO: 11, classification dependent upon the nature of the inventions.

J. The inventions as they pertain to SEQ ID NO: 13, classification dependent upon the nature of the inventions.

K. The inventions as they pertain to SEQ ID NO: 33, classification dependent upon the nature of the inventions.

L. The inventions as they pertain to SEQ ID NO: 34, classification dependent upon the nature of the inventions.

5. The inventions are distinct, each from the other because of the following reasons:

d. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOS: 1-4, 6, 8-11, 13, and 33-34 is a unique sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A CXCR4 agonist peptide and method of using the peptide, wherein the peptide comprises an N-terminal sequence and a C-terminal sequence, wherein the C-terminal sequence is homologous to:

aa. an SDF-1 C-terminal sequence

bb. a MIP-1α sequence

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 23 are generic, for example.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

A CXCR4 agonist peptide and method of using the peptide, wherein the peptide further comprises:

cc. an internal cyclic amide bridge formed between a carboxylic acid side chain on a first amino acid residue and an amine side chain on a first amino acid residue and an amine side chain on a second amino acid residue

dd. an internal cyclic disulphide or lactam bond between two amino acids

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 9, and 23 are generic, for example.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

A CXCR4 agonist peptide that is encoded by a nucleic acid that hybridizes under stringent conditions to a portion of a nucleic acid encoding:

ee. SDF-1alpha

ff. SDF-1beta

gg. SDF-1 precursor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 7 are generic, for example.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In order to be fully responsive, Applicant must select one from Groups I-IV and one from Groups A-L. Applicant is advised that neither I-III nor A-L are species election requirements; rather, each of I-IV and A-L is a restriction requirement.

If applicant selects Groups I, II or IV, one species from each of the CXCR4 agonist groups must be chosen to be fully responsive.

If Applicant selects Groups I or II, one species from the SDF group must be chosen to be fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
11 August 2004

Bridget E. Bunner